

### REMARKS

Claims 56-106 are currently pending in this application. Claims 87-106 are withdrawn from consideration. Claims 56-86 are rejected. Applicants amend claims 56, 79 and 81 to clarify that the point "lie[s] substantially on the longitudinal centre line of the needle."

#### Rejections under 35 U.S.C. 112

Claims 61, 63 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention.

Applicants cancel claim 61 and amend claims 63 and 82 to clarify "the opening is arranged on one and the same half of a cross section of the needle," as disclosed on page 7, lines 7-9 and in figure 1 of the published PCT-application.

Accordingly, Applicants request withdrawal of the rejections under Section 112.

#### Rejections under 35 U.S.C. 102

Claims 56, 57, 61-64 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson (U.S. Pat. No. 3,064,651). Applicants respectfully traverse as set forth below.

The needle point disclosed by Henderson is arranged to lie on the outer perimeter or sidewall of the needle, i.e. off-center from the central bore 11 (see figures 3 and 6).

In contrast, amended independent claim 56 recites a needle in which "the point is arranged to lie substantially on the longitudinal center line of the needle." This allows the claimed needle to be self-centering and non-coring irrespective of rotation about the longitudinal axis of the needle.

Henderson's needle addresses plug coring so far as it leaves a portion of the cored membrane intact. However, if Henderson's needle were used to penetrate a membrane

repeatedly while being rotated about its own longitudinal axis, it would result in the pattern of penetrations shown in figure 4a of the present application.

In contrast, Applicants realized that if the point of the needle is arranged to lie substantially on the longitudinal centre line of the needle and the needle opening edges are rounded, coring is substantially prevented even with multiple penetrations in the same location (as illustrated in figure 4 of the application), and even if the needle is rotated about its own longitudinal axis between penetrations.

Thus, the self-centering and non-coring aspects of the claimed needle allow for repeated penetration of a membrane without coring, irrespective of needle rotation, even in substantially the same location. As stated, this significantly reduces the risk of leakage and contamination.

Regarding the interpretation of “arranged to lie substantially on a longitudinal centre line of the needle,” Applicants submit that this cannot be reasonably interpreted to mean simply appearing to be coincident with a particular midpoint or single axis of symmetry when observed from a particular angle. Rather, substantially symmetrical, longitudinal bodies are generally understood to have a longitudinal center line, with “center” being understood in a two-dimensional sense when viewing the longitudinal object from an end. Thus, the recited point lies on the center line of the recited needle.

Accordingly, Applicants submit that Henderson does not disclose at least a needle in which the “penetrating tip is designed with a point to initially prick a membrane when the membrane is penetrated and that the outer edges present on the pointed end in the area from the point to a position beyond the opening are rounded so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane material; and wherein the point is arranged to lie substantially on a longitudinal centre line of the needle,” as recited in amended independent claim 56.

Accordingly, Applicants submit that independent claim 56 and dependent claims 57, 61-64 and 81 are patentable over Henderson.

Accordingly, Applicants request withdrawal of the rejections under Section 102.

Rejections under 35 U.S.C. 103

(1) Claims 58, 60, 76, 78-80, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson as applied to claim 56 and further in view of Hickey (U.S. Pat. No. 2,697,438).

(2) Claims 70, 71, 74, 75, 85 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson and Bittner (U.S. Pat. No. 5,515,871 as applied to claim 65 or Henderson, Bittner, and Haindi (U.S. Pat. No. 4,889,529) as applied to claim 69 or Henderson, Bittner and Hickey as applied to claim 84 and further in view of Kaneko (U.S. Pat. No. 6,517,523).

It should be noted that both Henderson and Hickey concern hypodermic needles, i.e. needles that are for single-use injection beneath the skin of a patient. Coring of tissues is of particular concern in this context. Another concern with hypodermic needles is patient pain reduction. Hypodermic needles are generally provided with sharp points and cutting edges as this is believed to minimize patient pain during insertion. (See U.S. Pat. No. 5,536,259 to Utterberg at col. 1, lines 11-12, 51-55; and U.S. Pat. No. 5,752,942 to Doyle at col. 2 lines 28-30).

In contrast, Applicants claimed needle is designed, for use with a synthetic membrane, e.g., a thermoplastic elastomer or silicone rubber membrane, and in particular, for repeated penetration of such membranes. Thus, pain or medical complications from tissue coring are perhaps less significant considerations than the sealing integrity of the synthetic membrane after repeated penetration with the needle.

The rounded edged needle disclosed by Henderson appears to address the problem of coring for a single-use penetration, even in the context of a synthetic membrane. Thus, one of ordinary skill in the art would have no reason to further modify the single-use needle disclosed by Henderson.

Applicants have realized, however, that if the point of the needle is arranged to lie substantially on the longitudinal centre line of the needle and the position of the centre line of the needle relative to a membrane is substantially maintained between the penetrations, penetration may be performed at one and the same point of the membrane (as illustrated in figure 4 of the present patent application) even at different rotational needle orientations, i.e., even when rotated about its own longitudinal axis.

The needle disclosed by Henderson would, if rotated and used to penetrate a membrane repeatedly, result in the pattern of penetrations shown in figure 4a of the specification. In contrast, the claimed needle may be used to repeatedly penetrate a membrane through the same hole due to the self-centering and non-coring features of the recited structures. This greatly reduces the risk of leakage and contamination.

The Office Action notes that Hickey discloses a needle having a point that is arranged to lie on the longitudinal centre line of the needle and Hickey makes no mention of any of the surfaces of the needle opening being rounded. Hickey proposed to solve the problem of coring through creating a downwardly curved surface 8 extending from a needle point positioned on the center line of the needle and providing upwardly curved bevels 10 extending from the point. (col. 2, lines 40-41). Hickey therefore discloses a completely different solution to the problem of coring. Even though Hickey discloses a point on the center line, Hickey does not indicate that there is any advantage when using a needle to repeatedly pierce a membrane with locating the point of a needle along a longitudinal centre line of a needle.

Absent Applicants' disclosure, one of mere skill in the art in possession of both Henderson and Hickey would not be motivated to arrive at the claimed configuration. In particular, a person of ordinary skill in the art would have no reason to combine the separate teachings of Henderson and Hickey in order to solve a coring problem that was independently addressed by the inventions described in each of the cited references.

Neither Bittner nor Haindi addresses the deficiencies of Henderson and Hickey. Thus, neither Henderson, Bittner, and Haindi, nor any combination of the same teach or suggest a

needle in which "the outer edges present on the pointed end in the area from the point to a position beyond the opening are rounded so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane material; and wherein the point is arranged to lie substantially on a longitudinal centre line of the needle," as recited in amended independent claim 56. Accordingly, Applicants submit that claim 56 and its dependent claims are patentable over the cited references.

Similarly, Applicants submit that neither Henderson, Bittner, and Haindi, nor any combination of the same teach or suggest a needle in which "point of the penetrating tip is arranged to lie substantially on the longitudinal centre line of the needle, and the penetrating tip is designed with a cross section having a symmetry causing at least three substantially equally sized forces (F) in different directions which are radial to the longitudinal centre line of the needle and which forces counteract each other so that the needle will tend not to deviate from the initial penetration direction when the needle penetrates a membrane," as recited in independent claim 76. Accordingly, Applicants submit that claim 76 and its dependent claims are patentable over the cited references.

Accordingly, Applicants request withdrawal of the rejections under Section 103.

### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

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Respectfully submitted,

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